IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP,	)	
Plaintiffs,	)	
v.	)	Civil Action No. _____
ZYDUS PHARMACEUTICALS (USA), INC., AND CADILA HEALTHCARE LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively "AstraZeneca" or "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code that arises out of the filing by Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, "Zydus") of an amendment to Abbreviated New Drug Application ("ANDA") No. 214263 with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Plaintiffs' Tagrisso® (osimertinib mesylate) in tablet form in doses of 40 mg and 80 mg prior to the expiration of U.S. Patent No. 10,183,020 ("the '020 patent").

PARTIES

Plaintiffs

2. Plaintiff AstraZeneca AB is a public limited liability company organized under the laws of Sweden, with a principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with a principal place of business at 1800 Concord Pike, Wilmington, Delaware, 19850.

Defendants

4. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus Pharma") is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

5. On information and belief, defendant Cadila Healthcare Ltd. ("Cadila") is a corporation organized and existing under the laws of India, with a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vasihnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

6. On information and belief, Zydus Pharma is a wholly owned subsidiary of Cadila, and is controlled and dominated by Cadila. On information and belief, Zydus Pharma is the U.S. agent for Cadila. Zydus has admitted in pending patent litigation concerning infringement of the '020 patent that Cadila is the manufacturer of Zydus Pharma's ANDA Products, and that Zydus Pharma is a wholly owned subsidiary of Cadila. *See AstraZeneca AB et al. v. Alembic Pharmaceuticals Limited et al.*, C.A. No. 20-202-RGA (D. Del. April 13, 2020) ("Pending Infringement Action"), D.I. 19 at ¶ 20.

7. On information and belief, Zydus Pharma is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Zydus Pharma, acting in concert with Cadila, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Zydus Pharma, acting in concert with Cadila, files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

8. On information and belief, Zydus Pharma and Cadila acted in concert to prepare, submit, and amend ANDA No. 214263 for their 40 mg and 80 mg osimertinib mesylate tablets ("Zydus's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Cadila.

JURISDICTION

9. Jurisdiction is proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

10. This Court has personal jurisdiction over each of Cadila and Zydus Pharma.

11. Cadila is subject to personal jurisdiction in Delaware because, among other things, Cadila, itself and through its wholly owned subsidiary Zydus Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Cadila, itself and through its subsidiary Zydus Pharma, develops, manufactures, imports, markets, offers to sell, and/or sells

generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Cadila is subject to personal jurisdiction in Delaware because, upon information and belief, it controls and dominates Zydus Pharma and therefore the activities of Zydus Pharma in this jurisdiction are attributed to Cadila.

12. Zydus Pharma is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Zydus Pharma, itself and in concert with Cadila, develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

13. On information and belief, Zydus knows and intends that following any approval of Zydus's ANDA No. 214263 as amended, Zydus will manufacture and import into the United States Zydus's ANDA Products and directly or indirectly market, sell, and distribute Zydus's ANDA Products throughout the United States, including in Delaware. On information and belief, following any FDA approval of ANDA No. 214263 as amended, Zydus knows and intends that Zydus's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

14. On information and belief, Cadila and Zydus Pharma are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic

pharmaceutical products throughout the United States, including into Delaware, and including with respect to Zydus's ANDA Products at issue. On information and belief, Zydus Pharma participated in, assisted, and cooperated with Cadila in the acts complained of herein.

15. Zydus has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

16. On information and belief, Zydus, with knowledge of the Hatch-Waxman Act process, directed Zydus's Second Notice Letter (defined below) to, *inter alia*, AstraZeneca Pharmaceuticals LP, to an address in Delaware, and alleged in Zydus's Second Notice Letter that the '020 patent will not be infringed by the commercial manufacture, use or sale of Zydus's ANDA Products. On information and belief, Zydus knowingly and deliberately challenged the '020 patent in its Second Notice Letter knowing that each time it did so it was triggering a forty-five day period for Plaintiffs to bring an action for patent infringement under the Hatch-Waxman Act.

17. Because AstraZeneca Pharmaceuticals LP is a limited partnership organized in Delaware, it suffers injury and consequences from Zydus's submission of an amendment to Zydus's ANDA No. 214263, and challenging the '020 patent in Delaware.

18. Zydus Pharma has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Zydus's Second Notice Letter to a Delaware entity, it would be sued in Delaware for patent infringement.

19. Cadila and Zydus Pharma regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court, *see, e.g.*, *Currax Pharmaceuticals LLC v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 19-1569-RGA, D.I. 11 (D. Del. Jan. 17, 2020); *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al.*, No. 19-1501-CFC, D.I. 9 (D. Del. Sep. 4, 2019); *Merck Sharp & Dohme Corp. v. Zydus Pharmaceuticals (USA) Inc.*, No. 19-314-RGA, D.I. 11 (D. Del. Mar. 18, 2019); *Astrazeneca AB v. Zydus Pharms. (USA) Inc.*, No. 18-664-RGA, D.I. 9 (D. Del. June 22, 2018); *Biogen Int'l GmbH v. Zydus Pharms. (USA) Inc.*, No. 18-623-LPS, D.I. 8 (D. Del. June 1, 2018); *H. Lundbeck A/S v. Zydus Pharms. (USA) Inc.*, No. 18-150-LPS, D.I. 13 (D. Del. Apr. 2, 2018); *Millennium Pharms., Inc. v. Zydus Pharms. (USA) Inc.*, No. 17-423-CFC, D.I. 9 (D. Del. May 24, 2017). Cadila and Zydus Pharma, in particular, presently are engaged in the Pending Infringement Action in this district. Accordingly, this Court has personal jurisdiction over Zydus.

20. On information and belief, if ANDA No. 214263 as amended is approved, Zydus will directly or indirectly manufacture, market, sell, and/or distribute Zydus's ANDA Products within the United States, including in Delaware, consistently with Zydus's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Zydus regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Zydus's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Zydus's ANDA Products will

be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. On information and belief, each of these activities would have a substantial effect within Delaware and would constitute infringement of the '020 patent in the event that Zydus's ANDA No. 214263 as amended is approved before the '020 patent expires.

21. On information and belief, Zydus derives substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Zydus and/or for which Cadila or Zydus Pharma is the named applicant on approved ANDAs. On information and belief, various products for which Cadila or Zydus Pharma is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

22. Venue is proper in this district for Cadila pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cadila is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

23. Venue is proper in this district as to Zydus Pharma under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Zydus Pharma is subject to personal jurisdiction in this judicial district, has previously consented to venue in this judicial district, and on information and belief is subject to venue in this judicial district and/or will consent to venue for the purpose of this case. Zydus Pharma has, in particular, consented to venue in related patent litigation in this district concerning infringement of the '020 patent in the Pending Infringement Action.

24. On information and belief, Cadila and Zydus Pharma are part of a broader network of affiliated entities sometimes called the Zydus group. On information and belief, entities affiliated with the Zydus group reside and/or maintain a regular and established place of

business within Delaware. Those entities include Zydus Healthcare (USA) LLC ("Zydus Healthcare")—which, on information and belief, is a limited liability company organized under the laws of Delaware—and Zydus Holding Inc. ("Zydus Holding")—which, on information and belief, is a corporation formed under Delaware law. On information and belief, each of Zydus Healthcare and Zydus Holding is a wholly owned subsidiary of Cadila and is controlled and dominated by Cadila.

25. On information and belief, the Zydus corporate family operates as a single, integrated business. On information and belief, Zydus Pharma, Cadila, Zydus Healthcare, and Zydus Holding are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Zydus's ANDA Products at issue.

26. On information and belief, Cadila maintains the website https://zyduscadila.com/. According to that website, "Zydus Cadila . . . is a fully integrated, global healthcare provider." (https://zyduscadila.com/company.) The website discusses "Zydus['s] . . . rich history and lineage," noting that, "[i]n 1995, the group was restructured and thus was formed Cadila Healthcare under the aegis of the Zydus group." On information and belief, Zydus entities often share directors and/or officers. For example, Mr. Pankaj R. Patel serves as chairman of Cadila's Board of Directors, and Dr. Sharvil P. Patel serves as Cadila's Managing Director (https://zyduscadila.com/investorzone). On information and belief, both men have served as directors of Zydus Pharma as well.

FACTUAL BACKGROUND

27. Plaintiffs incorporate each of the preceding paragraphs 1–26 as if fully set forth herein.

28. The ’020 patent, entitled “Pharmaceutical Compositions Comprising AZD9291,” (Exhibit A hereto), was duly and legally issued on January 22, 2019, to AstraZeneca AB.

29. As set forth in greater detail in the ’020 patent, the claims of the ’020 patent, incorporated by reference herein, cover pharmaceutical compositions comprising osimertinib mesylate and methods of using them.

30. AstraZeneca AB is the assignee of the ’020 patent.

31. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208065 for Tagrisso® (osimertinib mesylate), which has been approved by the FDA. Tagrisso® is a kinase inhibitor indicated for (i) “as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test”; (ii) “the first-line treatment of adult patients with metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test”; and (iii) “the treatment of adult patients with metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, whose disease has progressed on or after EGFR TKI therapy.” Tagrisso® is for oral use and is available as tablets in 40 mg and 80 mg dosage strengths.

32. Pursuant to 21 U.S.C. § 355, the ’020 patent has been listed in connection with Tagrisso® in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence*

Evaluations, which is referred to as the "Orange Book." The '020 patent is associated with, *inter alia*, use code U-3016 in the Orange Book.

33. AstraZeneca will be substantially and irreparably damaged by infringement of the '020 patent.

COUNT I – ZYDUS'S INFRINGEMENT OF THE '020 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

34. Plaintiffs incorporate each of the preceding paragraphs 1–33 as if fully set forth herein.

35. By letter dated January 14, 2020, Zydus notified Plaintiffs that it had submitted to the FDA ANDA No. 214263, seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of Zydus's ANDA Products prior to the expiration of the '020 patent ("Zydus's First Notice Letter"). On information and belief, the purpose of the submission of ANDA No. 214263 was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Products prior to the expiration of the '020 patent.

36. In Zydus's First Notice Letter, Zydus also notified Plaintiffs that, as part of ANDA No. 214263, Zydus had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '020 patent. On information and belief, Zydus submitted ANDA No. 214263 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '020 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products.

37. Subsequent to receiving Zydus's First Notice Letter, AstraZeneca sued Zydus for infringement of the '020 patent on February 11, 2020 in this district in the Pending Infringement Action.

38. By letter dated March 3, 2021, Zydus notified Plaintiffs that it had amended ANDA No. 214263 "to include a revised certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ('Paragraph IV Certification') to address the patent use code U-3016, with respect to" the '020 Patent ("Zydus's Second Notice Letter"). On information and belief, Zydus's ANDA No. 214263 as amended contains an amended certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '020 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products. Zydus's Second Notice Letter indicates that Zydus seeks approval from the FDA to engage in the commercial manufacture, use and/or sale of Zydus's ANDA Products prior to the expiration of the '020 patent. On information and belief, the purpose of amending ANDA No. 214263 was to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Zydus's ANDA Products prior to the expiration of the '020 patent.

39. According to information in Zydus's Second Notice Letter, Zydus's ANDA Products are a generic version of Tagrisso® tablets.

40. On information and belief, Zydus's ANDA Products are not publicly available, nor is ANDA No. 214263 as amended accessible to the public.

41. Plaintiffs are filing this Complaint within forty-five days of receipt of Zydus's Second Notice Letter.

42. According to Zydus's Second Notice Letter, Zydus's ANDA Products contain osimertinib. On information and belief, the osimertinib in Zydus's ANDA Products is in

the form of osimertinib mesylate. On information and belief, Zydus's ANDA Products contain osimertinib mesylate in an amount that literally satisfies the requirements of claim 1 of the '020 patent.

43. On information and belief, Zydus's ANDA Products are in the form of oral tablets for pharmaceutical use. Accordingly, Zydus's ANDA Products are pharmaceutical tablets.

44. On information and belief, Zydus's ANDA Products contain inactive ingredients that satisfy, literally and/or by equivalents, the limitations of claim 1 concerning materials other than osimertinib mesylate that are contained in the claimed pharmaceutical composition. Zydus's Second Notice Letter did not contest that Zydus's ANDA Products literally satisfy various limitations of claim 1 of the '020 patent.

45. On information and belief, and in light of Zydus's Second Notice Letter, the proposed amended product labeling for Zydus's ANDA Products provides, *inter alia*, that Zydus's ANDA Products are indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test. The proposed amended product labeling for Zydus's ANDA Products thus directs, encourages, and induces a method of treating cancer in a patient in need thereof, which method comprises the oral administration of an effective number of tablets that are Zydus's ANDA Products to the patient, wherein the cancer is non-small cell lung cancer.

46. In Zydus's Second Notice Letter, Zydus did not contest the validity of any claim of the '020 patent.

47. Zydus has now, and has had since at least before submitting ANDA No. 214263, knowledge of the '020 patent.

48. Zydus's submission of the amendment to ANDA No. 214263 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus's ANDA Products before the expiration of the '020 patent was an act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A).

49. On information and belief, Zydus will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Zydus's ANDA Products, together with their proposed amended product labeling, immediately and imminently upon approval of ANDA No. 214263 as amended and expiration of any other Orange Book-listed patent or relevant exclusivity for Tagrisso®.

50. On information and belief, the manufacture, use (including the use of Zydus's ANDA Products in accordance with, and as directed by Zydus's proposed amended product labeling for Zydus's ANDA Products), sale, offer for sale, and/or importation of Zydus's ANDA Products would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '020 patent, including at least claims 1, 8, 9, and 11-13.

51. On information and belief, Zydus plans and intends to, and will, actively induce infringement of the '020 patent when ANDA No. 214263 as amended is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

52. On information and belief, the foregoing actions by Zydus constitute and/or will constitute infringement of the '020 patent and active inducement of infringement of the '020 patent.

53. Unless Zydus is enjoined from infringing the '020 patent and actively inducing infringement of the '020 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY ZYDUS OF THE '020 PATENT

54. Plaintiffs incorporate each of the preceding paragraphs 1–53 as if fully set forth herein.

55. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on the one hand and Zydus on the other regarding Zydus's liability for infringement and active inducement of infringement of the '020 patent.

56. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Products will infringe and induce the infringement of the '020 patent.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Zydus has infringed the '020 patent;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Zydus's ANDA Products be not earlier than the expiration of the '020 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Zydus, and all persons acting in concert with Zydus, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Zydus's ANDA Products prior to the expiration of the '020 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Zydus's ANDA Products prior to the expiration of the '020 patent will infringe and induce the infringement of the '020 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Respectfully submitted,

Dated: April 16, 2021

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*
Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP

OF COUNSEL:

Jessamyn S. Berniker
Dov P. Grossman
Vidya A. Mirmira
Christopher A. Yeager
Jingyuan Luo
Sumeet P. Dang
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000
(202) 434-5029 (Facsimile)